

ATTACHMENT 28

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

IN RE: DA VINCI SURGICAL
ROBOT ANTITRUST LITIGATION

THIS DOCUMENT RELATES TO:) Lead Case No. 3:21-cv-03825-VC
ALL CASES)

SURGICAL INSTRUMENT SERVICE)
COMPANY, INC.,)

Plaintiff,)

vs.)

INTUITIVE SURGICAL, INC.,) Case No. 3:21-cv-03496-VC
)

Defendant.)

REMOTE VIDEOTAPED DEPOSITION OF
T. KIM PARNELL, Ph.D.
Friday, March 10, 2023
Volume I

Reported by:
NADIA NEWHART
CSR No. 8714
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SURGICAL INSTRUMENT SERVICE
COMPANY, INC.,

Plaintiff,

vs.

INTUITIVE SURGICAL, INC.,

Defendant.

Remote videotaped deposition of
T. KIM PARNELL, Ph.D., Volume I, taken on behalf of
Defendant Intuitive Surgical, Inc., with all
participants appearing remotely via videoconference
and the witness testifying from San Jose,
California, beginning at 9:16 a.m. and ending at
4:57 p.m. on Friday, March 10, 2023, before
NADIA NEWHART, Certified Shorthand Reporter No. 8714.

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Page 3

1 one at that time. So I didn't know about it before.

2 Q Okay. Did you change your opinions at all
3 from the Rebotix case to the opinions you're
4 offering here to account for the Court's ruling on
5 the Daubert motion in the Rebotix case? 09:47:10

6 MR. SNYDER: Objection to form.

7 THE WITNESS: I don't believe so. I -- I, of
8 course, did try to be cognizant of what the judge
9 had said. You know, when writing my report, that
10 kind of thing, I tried to be -- be thoughtful of 09:47:28
11 what the judge had said. I know -- I know there's a
12 different judge associated with this case.

13 And, certainly, I would expect that Daubert
14 motions and whether they're upheld or not upheld can
15 be dependent on the judge and how the judge views 09:47:45
16 the proceedings.

17 So the answer is no, I did not change my
18 opinions. I tried to be thoughtful as to how I
19 expressed my opinions, but my opinions -- I've tried
20 to be very consistent between Rebotix and between 09:48:05
21 the cases here for SIS and the hospital plaintiffs.
22 I've tried to be -- I've tried to be consistent
23 throughout.

24 BY MR. CHAPUT:

25 Q Okay. So just so I'm clear, as you were 09:48:17

1 drafting your reports in these matters, you tried to
2 be thoughtful about the Court's opinion in Rebotix,
3 but your opinions have not changed from Rebotix to
4 these cases, correct?

5 MR. SNYDER: Objection to form. 09:48:31

6 THE WITNESS: I believe that's true. That's
7 certainly my intention. If there's something you
8 want to show me to -- to -- for me to consider and
9 address, I'm happy to do so, but I believe my
10 opinions were consistent and were the same. 09:48:48

11 I may have developed some additional opinions
12 in these matters as they -- I was able to access
13 additional testimony, additional testimony on behalf
14 of the plaintiffs and additional testimony on
15 different Intuitive Surgical employees and maybe 09:49:08
16 experts -- well, experts and employees, but I
17 believe I've been very consistent throughout.

18 BY MR. CHAPUT:

19 Q Who drafted your reports in these cases?

20 A I did. And I worked with counsel on my 09:49:25
21 reports, but I drafted my reports, and the opinions
22 expressed there are my opinions.

23 Q Did counsel for SIS provide any assumptions
24 to you that you relied on in drafting your SIS
25 reports? 09:49:44

1 everything.

2 I think I answered your question directly and
3 completely by reading paragraph 2 and paragraph 3
4 from this report. I hope you wouldn't object to me
5 doing that. 09:59:14

6 Q Do your January and March SIS reports contain
7 all of your opinions in the SIS matter?

8 A Well, as I said in this report, probably in a
9 particular paragraph here somewhere below, I said
10 that they contain all the opinions that I developed 09:59:29
11 to date at that point.

12 I always reserve the right to consider new
13 information that may come about or -- or, really,
14 anything that may come about subsequent to the
15 report that I may need to consider and evaluate if 09:59:48
16 they change my opinions.

17 But as of the date of these reports, I
18 believe they were complete in terms of my opinions.
19 That was my intent, that they were complete.

20 Q Do your January and March SIS reports contain 10:00:03
21 all of the bases for your opinions in the SIS
22 matter?

23 A And what are bases, in your view?

24 Q Do your January and March SIS reports contain
25 all of the facts and data that you considered in 10:00:20

Page 40

1 forming your opinions in that case?

2 A Again, to the best of my ability, they do.

3 If there is something more that I need to talk
4 about, read, add another document, I would do that.

5 But, again, my attempt was to be complete. 10:00:45

6 My attempt was to be complete in laying out
7 what -- what was underlying my opinions and -- and
8 also in terms of providing my opinions.

9 MR. CHAPUT: I'd like to look at what we've
10 previously marked as Exhibit 277. 10:01:03

11 (Exhibit 277 was marked for identification
12 and is attached hereto.)

13 THE WITNESS: Okay. That's the third one on
14 doc share, then, right?

15 MR. CHAPUT: That's correct. 10:01:11

16 THE WITNESS: Okay. All right. I have it.

17 BY MR. CHAPUT:

18 Q Exhibit 277 is a copy of your report in the
19 hospital matter, dated March 1st, 2023?

20 A Yes. That's what I see on the first page. 10:01:26

21 And -- and as you certainly know, the plaintiff here
22 is listed on the report caption and the case caption
23 for the Court in regarding Da Vinci Surgical Robot
24 Antitrust Litigation.

25 So my understanding is this is an antitrust 10:01:42

1 litigation. There are a number of plaintiffs
2 associated with it. And, yes, I frequently refer to
3 it as a hospital report, and I think you're doing
4 the same now calling it a hospital report, because
5 there is a group of hospitals that are party to 10:02:00
6 this.

7 Q Does your hospital report contain all of your
8 opinions in the hospital matter?

9 A Same answer I gave before. I can repeat it
10 if you'd like, but I tried to be complete. I tried 10:02:19
11 to include all of my opinions, to the best of my
12 ability, and I tried to outline the things, the
13 documents, the -- the discovery, the things that I
14 evaluated in coming to those opinions.

15 And I, as in the other report, same language, 10:02:38
16 that I reserve the right to consider additional
17 information that may come to my attention later
18 after the report is filed and to evaluate if it
19 provides me with new opinions or if it modifies any
20 of my existing ones. 10:02:56

21 But to the best of my ability, this report
22 included my opinions as they stood on March 1st,
23 2023.

24 Q Does your hospital report contain all of the
25 facts and data that you considered in forming your 10:03:09

1 into my report other than it was context and it gave
2 me a better understanding of what they had done and
3 how it compared to Rebotix.

4 Q So apart from the tour that you described,
5 did you discuss anything else with Mr. Posdal during 10:32:09
6 your meeting in January?

7 A I mean, I tried to give you the highlights
8 there. If there's something specific -- I don't --
9 I don't recall anything else specific. You might
10 help to remind me of something. But I don't believe 10:32:35
11 there was anything else specific other than
12 background; how his company was organized; how they
13 were planning to do it, do the work of repairing
14 EndoWrists; what they had looked at for partners.
15 Those were the kind of things that I can recall 10:32:50
16 right now.

17 Q Okay. You have some experience with the
18 process of designing medical devices, correct?

19 A Yes.

20 Q Now, when you're designing a medical device, 10:33:06
21 there are typically a number of considerations that
22 the design team needs to take into account when --
23 or during the process, right?

24 A Certainly, design of anything, medical
25 devices, just like any other device, have a lot of 10:33:21

1 considerations and, in some cases, maybe
2 considerations that a food processor wouldn't have,
3 for example. But everything has a certain number of
4 considerations and manufacturability, things like
5 that, that have to be brought in, definitely. 10:33:39

6 Q As one example, the design team needs to
7 define what the customer's needs are; is that right?

8 A Typically, yes. Typically, that's very
9 important.

10 Q And so what the customer needs will impact 10:33:57
11 the design decisions that are made along the
12 process?

13 A It can, certainly, especially if it's a
14 highly customer facing type of component. You know,
15 I would distinguish something that's used by an 10:34:14
16 astronaut in a space shuttle or in -- in the sky lab
17 versus something that's used by a homeowner in their
18 kitchen, you know, very different. Very different
19 audience, you know, that kind of thing.

20 But both the user needs to be considered -- 10:34:37
21 if the user is the world or if the user is a highly
22 trained type of person, those can make things
23 different.

24 Q So to use an example from your own experience
25 in the medical device space, when you're designing a 10:34:54

1 stent, you have multiple options for the material
2 that you use for that stent, right?

3 A Possibly, depending on -- for example, if you
4 want a self-expanding stent, you don't have too many
5 options. Like Nitinol or shape memory alloy, that's 10:35:16
6 a primary thing that can be used for a
7 self-expanding stent.

8 If you're going to have a balloon expandable
9 type of stent, there are several different materials
10 that are commonly used. 10:35:29

11 Q So, for example, it might be made of metal or
12 some sort of composite and another material; is that
13 right?

14 A Well, not -- not typically. There are
15 several metal alloys that are used commonly. That's 10:35:44
16 true, for balloon expandable stents. There are some
17 stents that have been at least developed or explored
18 or things like that out of bioabsorbable materials,
19 and those are typically not metals.

20 Those may have -- those are -- the idea is 10:36:06
21 that a bioabsorbable material is that the stent will
22 be absorbed by the body and will effectively go away
23 over some period of time.

24 There are also stents that have -- they're
25 called drug-eluting stents, and so they have -- they 10:36:22

1 have pores or holes or receptacles and there's drugs
2 that are placed in those. Those are -- the ones
3 I've see are more typically some type of metal
4 alloy, not a bioabsorbable, and the drug is consumed
5 over some period of time. It may be weeks to 10:36:41
6 months, you know, something like that, depending on
7 a lot of parameters.

8 Q And the team has to consider all of those
9 different parameters and how the stent is going to
10 be used in deciding ultimately how to design that 10:36:54
11 particular product, right?

12 A I mean, I think we're sort of circling around
13 here, but sure. For anything there are always
14 design considerations. There are -- there are
15 things that -- usually performance things, cost 10:37:09
16 things, manufacturability things.

17 There's a whole host of things that would go
18 on a shopping list for a design team for anything.
19 In a stent, there's a shopping list associated with
20 stents also. 10:37:29

21 Q Apart from the set of cases against
22 Intuitive, have you ever been engaged to offer
23 opinions about minimally invasive surgical
24 instruments specifically?

25 A I believe the answer is yes. 10:37:44

1 was an implantable device, a coronary device and
2 Nitinol self-expanding.

3 Now, here's one, CrossRoads Extremity
4 Systems. I did a lot of work here. These are in a
5 totally different category. 10:52:34

6 These are not catheter-delivered devices but
7 used for bone fixation, focused on foot and ankle,
8 staples, plates, things like that. They came under
9 a 510(k.) I did a lot of work on those.

10 Q Right. And so that -- the CrossRoads would 10:52:51
11 be an example of the screws or plates that you had
12 mentioned before, correct?

13 A Well, they didn't have screws. That was the
14 unique part. You could do fixation and stuff with
15 staples that were -- that were Nitinol or shape 10:53:09
16 memory material. You could do fixation with staples
17 as opposed to screws and plates and things.

18 But then there were also some things that you
19 might call plates, but they didn't need screws, as I
20 recall. They had -- they utilized the shape memory 10:53:25
21 alloy part to provide forces to achieve repair and
22 regrowth and fixation. So they were different.

23 They were innovative devices that took the
24 place of something that required a much more open
25 procedure, a lot of screws and things of that sort. 10:53:43

1 They -- they were improvements there.

2 Q And, again, I'm just trying to understand,
3 what are the categories of devices that you've
4 worked on? So the next one that I see is the Design
5 Standards Corporation. That's a clip, and you've 10:53:59
6 also mentioned clips, correct?

7 A Surgical ligation clips. No, I haven't
8 mentioned this type. This is -- this could be used
9 in a -- a minimally invasive surgical procedure of a
10 variety of types. Just like you need suturing, you 10:54:23
11 know, you need to sew things through a cannula. You
12 also sometimes use clips or staples to close tissue,
13 because they can be deployed quickly.

14 They can still go through a minimally
15 invasive cannula type of device, but they do a 10:54:40
16 different thing. You know, they're not cutting
17 tissue, but they're closing tissue or closing off
18 blood flow or things like that.

19 Does that help?

20 Q Again, sir, I'd like you to focus on my 10:54:55
21 question. And I'm just trying to understand the
22 type of device that we were just looking at is a
23 clip, correct?

24 A Yes --

25 Q Okay. 10:55:09

1 A -- it's a clip.

2 Q The next one is Sirius Engineering, and you
3 described that as an implantable cardiovascular
4 medical device, correct? So that's an implantable
5 device? 10:55:21

6 A For the vena cava filter. Very different
7 application from one place versus another. That's
8 what I'm trying to bring out for you, is that --
9 that different applications require different
10 devices. 10:55:36

11 They replace different types of procedures.
12 That's all I'm trying to explain, but, yeah, go
13 ahead. Ask your question.

14 Q Thank you. And I appreciate that.

15 You can -- you can set that aside for now. 10:55:50

16 A You don't want to go through others?

17 Q I think we've seen enough examples. Thank
18 you, sir. You can set that aside.

19 A Okay.

20 Q So I have not heard you identify any 10:56:05
21 minimally invasive surgical instruments where what
22 you have worked on is the instrumentation that the
23 surgeon uses to perform the operation.

24 A I --

25 MR. SNYDER: Objection to the form. 10:56:27

1 THE WITNESS: Yeah, I -- I think I have, sir.

2 I think I've illustrated several things there. If I
3 haven't done it adequately to explain it to you, you
4 can ask some additional questions, but I think I've
5 illustrated a number of devices that fall exactly 10:56:45
6 into that category.

7 BY MR. CHAPUT:

8 Q Have you ever observed a laparoscopic surgery
9 performed start to finish?

10 A Start to finish. I believe the answer is 10:57:04
11 yes. I've certainly observed many portions thereof.
12 You know, sometimes -- sometimes the very start to
13 the very finish. There's a number of other things
14 with setting up the patient, draping, things like
15 that, but I believe the answer is yes, and I've 10:57:25
16 absolutely watched portions of procedures a number
17 of times.

18 Q And when you say that, you're speaking
19 specifically about laparoscopic procedures?

20 A Yes. 10:57:40

21 Q Have you ever observed a robotic-assisted
22 surgery performed in its entirety?

23 A Again, same answer with regard to entirety
24 that you've put in there. I mean, probably entirety
25 means from the start of the setup of the procedure 10:57:58

Page 71

1 to the time where the last instrument is taken out
2 and the patient comes in in the middle and goes out
3 somewhere before the end.

4 But I -- I have absolutely watched portions
5 of those procedures that were of more interest to me 10:58:12
6 as opposed to the setup and the takedown.

7 Q Do you recall testifying in your Rebotix
8 deposition that you had seen probably less than ten
9 surgeries performed using a Da Vinci surgical
10 system? 10:58:29

11 A I don't recall that specifically. If you
12 want to point me to it.

13 Q Sure. Let's look at Exhibit 278. We're
14 going to page 30 of the deposition transcript. This
15 appears on page 9 of the document. 10:58:46

16 A Wait a minute. Oh, oh, okay. Because
17 there's four to a page here. Okay. Page 9?

18 Q Page 9. And you'll see page 30 of the
19 transcript appears in the top left corner.

20 A Okay. Got it. Okay. Now I see it, yes. 10:59:06

21 Q I'm looking at lines 19 through 22. Do you
22 see that? (As read):

23 "How many different surgeries do you
24 say you have observed either
25 personally or electronically that 10:59:25

Page 72

1 were carried out with the Da Vinci
2 Surgical system?

3 "Answer: I would estimate probably
4 less than ten."

5 Do you see that? 10:59:29

6 A I'm reading here. Okay. At -- near the
7 bottom of page 30. Yes, and this was September --
8 date of this depo was September 24th, 2021.

9 Q Since that time, have you seen any additional
10 surgeries using a Da Vinci surgical system? 10:59:41

11 A Yes.

12 Q How many?

13 A I don't know. I don't have a count, but it's
14 certainly been some additional number of surgeries
15 being carried out that way. 10:59:55

16 Q How did you see those surgeries? Did you
17 watch them on video, or did you see them in person?

18 A Since the date of this depo in
19 September 2021, I have not been invited to witness
20 anything in person. I think it would -- I think it 11:00:13
21 was all video recordings of surgeries, to the best
22 of my recollection.

23 Q Since September of 2021, have you seen more
24 than five videos of Da Vinci surgical -- excuse me.

25 Since September of 2021, have you seen more 11:00:33

1 than five videos of surgeries performed using a
2 Da Vinci surgical system?

3 A I believe the answer is yes, but I don't have
4 a log of exactly specific ones, date I watched or
5 anything, but I tried to look at -- I tried to get 11:00:52
6 more experience with the use of the Da Vinci for
7 different types of surgical applications.

8 And so I searched, you know, for things like
9 that that utilized the Da Vinci and EndoWrist being
10 applied for different types of procedures. So I 11:01:11
11 think the answer is more than five, based -- based
12 on that, because there's quite a number of different
13 procedures that the Da Vinci is frequently utilized
14 on.

15 Q Are you relying on those additional surgeries 11:01:25
16 that you watched on video in reaching your opinions
17 in these matters?

18 A I think the answer is no. They provide
19 context. They provide understanding of the process
20 that goes on in use of an instrument, process 11:01:44
21 involved with swapping an instrument, mounting it to
22 the Da Vinci, that kind of thing.

23 But I don't recall any of those that showed
24 any kind of failure or upset condition that I
25 recall, you know, that required an EndoWrist to be 11:02:04

1 A So did I -- if I did it before these matters,
2 did I do it again? I'm not sure. I don't think so.
3 I think these are -- the best of my recollection, I
4 had the opportunity to see instruments previously,
5 like in my visits to Stanford, visits with doctors 11:17:22
6 at Stanford.

7 I participated in a number of types of things
8 by design types of projects at Stanford. It was
9 probably associated with that, but I don't recall
10 directly the when of that. Those would have been 11:17:44
11 before these cases though.

12 Q You don't recall what laparoscopic
13 instruments you've inspected in the past?

14 A Well, they -- like, for example, Dr. Howe
15 shows a couple of photos of what I would call 11:18:08
16 traditional laparoscopic instruments in his report.
17 They were similar to that.

18 I mean, there are -- just like there must be
19 over a hundred EndoWrists, you know, with different
20 types of suturing, cutting, grasping types of 11:18:22
21 capability, there are different standard Endo- --
22 not standard EndoWrists, standard laparoscopic
23 devices that do different things.

24 You know, they're not multifunctional, per
25 se, but they -- there are some that would cut. 11:18:39

1 There are some that would grasp, forceps, things
2 like that. I don't recall specifically.

3 I couldn't tell you a manufacturer or a
4 specific type, but they were -- they were
5 representative of what Dr. Howe showed in his 11:18:56
6 report. So I didn't go looking for additional ones,
7 I guess, as a result. I felt like I was familiar
8 with those devices.

9 Q You don't recall seeing any laparoscopic
10 instruments in the past that looked different from 11:19:10
11 the laparoscopic instruments that there were
12 photographs of in Dr. Howe's report?

13 A I -- I'm not sure how to answer that. I
14 think I saw several types. In fact, I'm not even
15 sure. I'd have to look at Dr. Howe's report again 11:19:27
16 to see exactly what he showed.

17 I just remember the part that the surgeon
18 interacts with in his report. I'm not sure that he
19 showed the tool end of the device, but maybe he did.
20 I'm going to -- do you have a particular page you 11:19:40
21 want me to look at?

22 Q No, that's okay. I'd like -- if you don't
23 mind, if we could focus on my question. Again, I'm
24 just trying to remember what you recall about the
25 laparoscopic instruments you've seen in the past. 11:19:59

1 know, a push-pull type of thing, you know, something
2 that rotates. It pushes a rod down -- down through
3 the shaft at the distal end; then it operates some
4 function.

5 You know, if it's scissors, it makes the 11:53:56
6 scissors come together in a cutting motion then.
7 You need typically two -- two things to make that
8 happen.

9 Q Sitting here today, are you aware of any
10 commercially available traditional laparoscopic 11:54:10
11 instrument that has cables?

12 A All right. So you're limiting it to
13 commercially available?

14 Q That's correct.

15 A As I sit here today, I'm not aware. But as I 11:54:27
16 said before, I mentioned some that I have seen
17 scientific papers, medical papers on. And whether
18 those have since been commercialized and I'm just
19 not aware of it, I couldn't say.

20 Q Moving forward to paragraph 42, you say here 11:54:40
21 just before the block quote that (as read):

22 "Failure modes on EndoWrists just
23 like on traditional laparoscopic
24 instruments are obvious," correct?

25 A Yes. That's paragraph 42, yes. 11:55:11

1 cited in -- later in the paragraph. They utilize
2 magnification up to 10X and typically at 10X when
3 looking at the finer details.

4 So 10X means that -- you know, something that
5 has a 2-millimeter length, you know, that the 12:12:41
6 inspector will see that and it will appear larger,
7 you know. It will be much more clear. Look at it
8 with the naked eye. That's tiny.

9 Certain things are very tiny, but you magnify
10 them by ten times, you make them bigger. You're 12:13:00
11 able to see things in greater detail under a mag- --
12 under a microscope or under some type of hand
13 magnification in inspection. Things are often done
14 like that where they bring it in.

15 They may photograph it also, but they'll 12:13:18
16 certainly look at it visually and try to examine it
17 carefully, try to operate things and look at it with
18 the magnification.

19 Q And you say that the -- at least 10X
20 magnification is a required part of the Rebotix 12:13:33
21 process?

22 A I believe so. From what I saw, from what was
23 explained to me when I was in Florida at the Rebotix
24 facility and -- yes, I believe I also read that in
25 their inspection procedure. I mean, the inspection 12:13:48

1 part is a critical piece here.

2 You don't just bring in any old EndoWrist and
3 repair it. You -- you identify ones that have
4 failures that are not appropriate to repair with
5 this kind of procedure and you screen those out. 12:14:08

6 And they frequently screened out instruments
7 that had something wrong that would not be
8 subject -- be appropriate for them to repair. That
9 certainly occurred.

10 They had a number of instruments that they 12:14:22
11 had received, and if the hospital didn't want it
12 back, they put it into their own inventory.

13 MR. CHAPUT: Let's take a look at the Rebotix
14 process. This is going to be Exhibit 279.

15 Austin, this is tab 21, the document with 12:14:40
16 Bates REBOTIX162404 through 424.

17 THE WITNESS: Okay. I don't have it yet. I
18 have tab 01 which was --

19 MR. CHAPUT: Yeah. It will -- it will be
20 there in just a moment. Just give it a sec. 12:14:57

21 THE WITNESS: Okay. And what exhibit? 279?

22 MR. CHAPUT: 279.

23 THE WITNESS: Okay. Yeah, I don't have it
24 yet.

25 MR. SNYDER: Yeah, I'm not seeing it yet 12:15:10

1 it was not a successful repair, and it would not be
2 sent back or it would go through the whole process
3 all over again.

4 Excuse me.

5 MR. CHAPUT: Why don't we go off the record, 12:54:39
6 and we can take a break for lunch.

7 THE VIDEOGRAPHER: We are off the record.
8 The time is 12:54 p.m.

9 (Lunch recess.)

10 (Mr. Corrigan left the proceedings.) 01:54:00

11 THE VIDEOGRAPHER: We are back on the record.
12 The time is 1:54 p.m.

13 BY MR. CHAPUT:

14 Q Dr. Parnell, what is ileocecal-colectomy?

15 A What's a what? I'm sorry? 01:54:24

16 Q An ileocecal-colectomy?

17 A Precisely? I don't know. I would look it
18 up. I know what it sounds like, but I won't
19 hazard -- it's a medical procedure. I'm sure of
20 that. 01:54:41

21 Q What's a -- how about a sigmoid colectomy?

22 A How do you pronounce -- how do you spell
23 colectomy? Colestomy?

24 Q C-o-l-e-s -- excuse me, c-o-l-e-c-t-o-m-y.

25 A Would you like me to look it up or just -- 01:54:55

1 Q No. If you don't know, that's fine.

2 A I -- I cannot define it for you right now.

3 I'm not a medical doctor. I am merely a Ph.D.

4 mechanical engineer with medical device training.

5 So I'm sorry. I don't know all of those things. 01:55:11

6 Q There's a section in your report in the
7 hospital case that starts on page 95. The heading
8 is "Inadequacies of the EndoWrist Use Counter."

9 A Oh, yeah. 95?

10 Q Page 95, yes. 01:55:31

11 A Okay.

12 Q Your opinion in this section is that the use
13 counter on Intuitive's EndoWrist is inadequate for
14 accurately tracking wear and tear; is that correct?

15 A Yes. 01:55:46

16 Q And you say that Intuitive already tracks
17 information that would allow it to measure wear and
18 tear based on the length of time an individual
19 EndoWrist is used in surgery?

20 A Well, to at least measure those parameters 01:56:02

21 like time. For example, in -- yeah, in the logs
22 that are collected and then also the My Intuitive
23 app, it shows time associated with a device in
24 different operations. So it's pretty clear that
25 they'll make that available or even have it 01:56:19

1 don't require any change. Those are all -- those
2 are all things that are apparently available, that
3 My Intuitive app tracks time, and apparently these
4 logs that are current, that would also include time.

5 If they track current versus time, then they 02:02:59
6 certainly have time, but they have more than time.
7 They have these things for each degree of freedom,
8 so --

9 Q But --

10 A -- not, I don't think it requires any 02:03:09
11 redesign of the EndoWrist. It requires
12 intelligently making use of data that they already
13 have with their Xi's, and it appears with their Si's
14 too, because I think the My Intuitive app said it
15 applies to both. 02:03:30

16 Q So at a minimum, Intuitive would have to
17 write new software and develop a use counter that
18 would expire the EndoWrists based on these factors
19 that you're talking about, correct?

20 MR. SNYDER: Objection. 02:03:41

21 THE WITNESS: You know, sir, I don't know on
22 that, because I haven't been asked to redesign an
23 EndoWrist or to interpret what they would need. I
24 could certainly talk about things that I would
25 consider and the things that I think should be 02:03:52

1 considered.

2 But as you pointed out, there's a lot of --
3 there's a lot of issues that have to be considered
4 in any kind of redesign. It does appear to me,
5 sitting here today -- with what I know, it appears 02:04:05
6 to me that the information is available that would
7 allow them to do these things right now without any
8 modification.

9 Now, what would they do with it? How would
10 they change their use counter? I would agree -- 02:04:20
11 here's one thing I would agree. I don't think you
12 want a device to expire during a procedure. So
13 you'd have to do it where any information that comes
14 from this comes at the end of a procedure, not
15 during a procedure. I would agree with that. But, 02:04:34
16 again, those are things that can all be done and not
17 done with a lot of complexity either.

18 BY MR. CHAPUT:

19 Q So you say they can be done, but you aren't
20 offering any opinion on how they would be done; is 02:04:49
21 that correct?

22 A If you ask me to, I can --

23 Q I'm asking about your report, sir. In your
24 report, you are not --

25 A Well, sir, my report -- we've talked about 02:05:00

1 what my report has. My report talks about ways that
2 they can do it, and it further goes on to things
3 that I've learned even subsequent to this report
4 that show even more so that they have the ability
5 right now without any additional work to do these 02:05:16
6 things.

7 Q So if you would let me finish my questions,
8 please.

9 A Sure.

10 Q I'm asking about your report. And you are 02:05:24
11 not offering an opinion as to how this redesigned
12 use counter that you propose would be done, correct?

13 MR. SNYDER: I've got to object just for a
14 clear record. I think you were both talking at the
15 same time. I don't think it was intentional. Let's 02:05:41
16 just move on.

17 THE WITNESS: I believe, sir -- I believe I
18 answered your question.

19 BY MR. CHAPUT:

20 Q You don't offer any opinion about how 02:05:56
21 Intuitive could measure mishandling or misuse in a
22 redesigned use counter, correct?

23 A I -- just like the other things we're talking
24 about, I did not attempt to redesign their device or
25 to redesign and implement a different criteria. I 02:06:16

1 do think, based on what I know, that there is
2 information that is readily available to them that
3 very well might be utilized directly to look at
4 misuse or mishandling. It might be. I don't know
5 yet.

02:06:34

6 Q Well, let's look at what you said in your
7 report. Let's go to paragraph 234.

8 A Okay.

9 Q And in the third sentence of that paragraph
10 you wrote (as read):

02:06:43

11 "The only way to accurately
12 determine whether an instrument has
13 been misused or mishandled is
14 through visual inspection and
15 testing."

02:06:51

16 Is that correct?

17 A That's the sentence that's here. We should
18 probably read the entire paragraph so it's got some
19 context. May I read the entire paragraph?

20 Q Feel free.

02:07:02

21 A Thank you. So paragraph 234, page 106
22 says -- and this is under the heading, the topic,
23 "The use counter does not take into account
24 mishandling or misuse."

25 So now, paragraph 233 before has a little bit 02:07:21

Page 154

1 place, how many rejected EndoWrists did you see when
2 you were at Rebotix's facility?

3 A Again, I'm going from memory here. It was
4 probably of the order of five to ten, but I do know
5 from representations made by Mr. Fiegel and -- and 02:18:47
6 Rebotix that I -- that I talked to before starting
7 to go through the lab and the process that they had
8 a lot of EndoWrists that did have some sort of
9 damage and that, from inspection, were deemed to not
10 be repair candidates. 02:19:09

11 Unsuitable for repair, that was a
12 designation. They put a sticker on the box,
13 "unsuitable for repair." And I think they put a
14 sticker on the EndoWrist, the housing also, as it
15 was, so that they wouldn't -- it wouldn't be brought 02:19:24
16 up accidentally again. They wanted anything that
17 they had already inspected to be out of the repair
18 picture.

19 Q Of the five to ten unsuitable-for-repair
20 EndoWrists you saw, who selected that set of five to 02:19:40
21 ten?

22 A As I recall, I think it was Mr. Fiegel,
23 although he showed me a large rack, storage area, if
24 you will, metal shelf storage area, that EndoWrists
25 were on. And they had a whole -- they had a whole 02:20:05

1 section that was strictly devoted to EndoWrists that
2 were unsuitable for repair. I don't think I went in
3 and randomly selected them. I think he brought out
4 some to show me but --

5 Q Did you -- I apologize. 02:20:19

6 A There were a lot that were available there to
7 select. I suppose I could have, you know, hunted
8 and selected and picked to look at. But I -- I
9 thought the ones that he might select to show me,
10 they seemed rather -- rather arbitrarily selected, 02:20:31
11 not pre-selected, not filtered, if that's what
12 you're getting at. I think he showed me a selection
13 that were representative.

14 Q I'm not getting at anything. I'm just trying
15 to understand the process. 02:20:50

16 Did you offer him any criteria that you were
17 interested in seeing when he was selecting those
18 unsuitable-for-repair EndoWrists?

19 A I think we talked about certain things, as I
20 recall. I believe we did. Again, going from 02:21:03
21 memory, but I believe we did talk about certain
22 things that would be useful to see.

23 Q What were those things that you thought would
24 be useful to see?

25 A Well, one would be various types of broken 02:21:17

1 cables or frayed cables, you know, ones that are
2 like in the photos starting on page 37. I think at
3 least one of these may have a complete cable break.
4 It looks like some have frayed cables. They're
5 certainly not functioning. 02:21:34

6 I think I asked about some that had damage,
7 like, you know, cracked shaft or wouldn't pass the
8 electrical test if it was a monopolar or bipolar
9 instrument, one that wouldn't pass the Hipot test or
10 other test for electrical isolation. 02:21:50

11 I believe I asked -- well, as I recall, I
12 think they had some that had zero on the use
13 counter. And, as you know, they specified that it
14 had to have one or more on the use counter to be
15 able to repair with their receptor chip. So there 02:22:14
16 were some that had zero, and those were not suitable
17 for repair.

18 So it was a variety of things. There was
19 damage, mechanical damage, breakage, electrical
20 damage where it wouldn't pass the electrical test. 02:22:27
21 Maybe it also might not even function. If it
22 wouldn't pass the Hipot test, it probably would not
23 function to cauterize or whatever the function of
24 that device was.

25 There were some that had -- that had 02:22:43

1 seriously deformed or distorted graspers or things
2 like that, scissors, ones that could not be
3 straightened with small adjustments, things that
4 cannot be fixed by sharpening of scissors. You
5 know, again, this is what I can recall. 02:23:05

6 We looked at a number of different things.
7 He could show, okay, this has this. I don't
8 remember if they were already labeled on the box
9 beyond unsuitable for repair or if he had -- he may
10 have had a log that showed a given device in their 02:23:17
11 inventory and what the issues were. I honestly
12 don't recall on that.

13 Q How long did you look at each of the
14 unsuitable-for-repair EndoWrists?

15 A Well, I know I was there in their lab for 02:23:37
16 approximately a business day. We got there early,
17 and we went until I had to leave for a flight in the
18 early evening going from Florida back to California.
19 I don't remember exactly what time I had to leave,
20 but I think it was -- it was not midnight. You 02:23:54
21 know, I think it was 5:00 or 6:00 p.m., maybe 7:00
22 p.m., something like that.

23 And so I think I was there from open -- open
24 business, maybe even early because I was coming from
25 the West Coast, and we wanted to get an early start 02:24:14

1 wear but one cable had broken, your conclusion is
2 that must have been due to damage.

3 Am I understanding you correctly?

4 A Well --

5 MR. SNYDER: Objection. 02:35:55

6 THE WITNESS: -- my conclusion is that it was
7 possibly that way, maybe even likely that way.

8 I can't say that it is absolutely
9 100,000 percent -- 100 percent that way, but it was
10 my belief -- my experience that looking at that, 02:36:10
11 that it looked like it appeared that one cable -- in
12 those circumstances, one cable had gotten damaged in
13 some mechanism, some external damage mechanism and
14 the others, by virtue of being -- still appearing
15 intact, still appearing to go through the pulleys 02:36:31
16 properly, maybe still even operating the -- you
17 know, their degree of freedom properly, that they
18 were not associated with wear. That was my
19 conclusion on a limited inspection though.

20 BY MR. CHAPUT: 02:37:01

21 Q I'd like to move to an aspect of your opinion
22 on Rebotix's life testing on page 57 of your
23 hospital report at paragraph 145.

24 A All right. Just a minute. 57 and 145
25 paragraph number? 02:37:16